UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA ex rel. PHARMA FRAUD WATCH LLC,	)	Case No. 1:10cv669
Plaintiff	)	COMPLAINT
v.	)	(Filed Under Seal)
BAYER SCHERING PHARMA AG, and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	JURY TRIAL DEMANDED
Defendants.	)	

Plaintiff UNITED STATES OF AMERICA ex rel. PHARMA FRAUD WATCH LLC alleges as follows:

NATURE OF THE CASE

1. This is an action for a violation of the False Claims Act by defendants. PHARMA FRAUD WATCH LLC brings this *qui tam* action as a relator on behalf of the United States of America.

PARTIES

2. Plaintiff PHARMA FRAUD WATCH LLC is a Texas limited liability company with a principal place of business in Houston, Texas.

3. Defendant BAYER SCHERING PHARMA AG is a German corporation.

4. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is a Delaware corporation. Its agent for service of process in Texas is Corporation Service Company, 211 East 7th Street, Suite 620; Austin, TX 78701-3218.

JURISDICTION AND VENUE

5. The Court has jurisdiction of this action under 28 U.S.C. § 1331 and 31 U.S.C. § 3729.

6. The Court has personal jurisdiction over defendants. Defendants conduct and have conducted substantial business within Texas, and this district, and have made significant sales of their products within Texas. Defendants have also offered for sale and advertised the products that are the subject of this complaint in Texas and in this district.

7. Venue is appropriate in this district under 28 U.S.C. § 1391(b) and (c).

FACTS

8. More prescription drugs are purchased through the Medicaid program than through any other insurance program in the United States. The federal government provides most of the funds used to purchase these pharmaceuticals. Not surprisingly, in order to prevent waste, fraud and abuse, the Medicaid program restricts the types and uses of drugs that may be paid for with federal funds. Additionally, federal regulations prohibit certain marketing practices that have a propensity to lead to the unnecessary and ineffective prescription of pharmaceuticals. These regulatory schemes are designed to insure that Medicaid only pays for drugs which are found to be safe and effective for their prescribed uses, and to insure that physicians who prescribe such drugs do not have ulterior motives for prescribing drugs that will be purchased with federal funds.

9. Defendants knowingly and deliberately engaged in conduct they knew would lead to the violations of federal Medicaid statutes and regulations designed to restrict Medicaid reimbursement for two of defendants' drugs: Yasmin and Yaz. Defendants did

not directly provide Yasmin or Yaz to the Medicaid program or issue prescriptions for the drugs. Instead, defendants embarked on a course of unlawful conduct that they knew would lead to the submission by physicians and pharmacists of Medicaid claims for Yasmin and Yaz when such prescriptions were not eligible for Medicaid reimbursement. Although most of the physicians and pharmacists were unaware that their Medicaid claims were ineligible for reimbursement, defendants knew their actions would inevitably cause these Medicaid providers to submit false claims to the federal government. Defendants caused these false claims to be presented to the United States for payment in violation of 31 U.S.C. § 3729.

10. New pharmaceutical drugs may not be marketed in the United States until the sponsor of the drug has proven to the Food and Drug Administration (FDA) that the drug is safe and effective for specific indications at specified dosages. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also approved by the FDA. Although it is not unlawful for physicians to prescribe approved drugs for indications, or at dosages, different than those set forth in a drug's labeling, The Food Drug and Cosmetic Act prohibits drug companies from marketing or promoting approved drugs for uses other than those set forth in the drugs' approved labeling. This regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body.

11. The Medicaid program also relies on the FDA's findings regarding what uses for approved drugs are safe and effective. In 1990, Congress passed the Budget Reconciliation Act which limited reimbursement for prescription drugs to "covered

outpatient drugs." Covered outpatient drugs include only drugs used for "medically accepted indications." A medically accepted indication is a use which has been approved by the FDA or one which is supported by specific compendia set forth in the Medicaid statute.

12. As described below, Defendants knowingly and intentionally violated the regulatory schemes described above in their marketing of Yasmin and Yaz. When they intentionally decided to employ these improper marketing practices to promote Yasmin and Yaz, Defendants knew or should have known that pharmacists and physicians would routinely and necessarily file false claims with the federal government when they sought federal reimbursement for Yasmin and Yaz prescriptions for off-label uses. But for Defendants' actions most, if not all, of the false claims for the prescription of Yasmin and Yaz for off-label uses would never have been filed. Although it did not directly contract with the federal government, Defendants were the indirect beneficiaries of all of the false claims described herein.

13. Yasmin and Yaz are not approved by the FDA for the purpose of treating women to produce the following three effects together: a contraceptive effect, an anti-androgenic effect, and an anti-aldosterone effect. Using Yasmin or Yaz in this manner is off-label. Indeed, defendants' argument that Yamin was approved by the FDA for this use was recently rejected as "frivolous" in a lawsuit pending in the Southern District of New York (case no. 1:08-cv-03710-PGG-JCF). *See* 9/28/2010 Order at 16 (Dkt. No. 161). Nor do any of the compendia referenced in the Medicaid statute support this off-label use.

14. Defendants deliberately decided to market Yasmin and Yaz for this off-label use. Defendants have admitted this in recent filings in a lawsuit in the Southern District of New York (case no. 1:08-cv-03710-PGG-JCF) ("New York Lawsuit"):

> In preparing to launch Yasmin®, Bayer's marketing department made a strategic decision to highlight the ***antimineralocorticoid*** and ***antiandrogenic*** effects of drospirenone, as well as its ***progestogenic*** effect, in Bayer's professional marketing campaign (i.e., materials aimed at professionals). This was seen as a means of differentiating Yasmin® from its competitors.

Declaration of Fadwa Almanakly ¶ 10 (Dkt No. 85-10). ("Anti-aldosterone" and "anti-mineralocorticoid" are synonyms. "Progestogenic effect" refers to a contraceptive effect.)

> Since the launch of Yasmin®, Bayer has promoted its use as an oral contraceptive that simultaneously induces ***contraceptive***, ***anti-mineralocorticoid***, and ***anti-androgenic*** effects.

Bayer's Opposition to the Generic Defendants' Motion to Dismiss at 21 (Dkt No. 84).

14. The use of Yasmin and Yaz for off-label use is widespread. For example, in the New York Lawsuit, defendants submitted a declaration of Dr. Lee Shulman, "a leading obstetrician-gynecologist with extensive experience in oral contraceptive research," stating that he "prescribes Yasmin®" for the purpose of producing anti-minaeralocorticoid and anti-androgenic effects in addition to a contraceptive effect "often." Bayer's Opposition to the Generic Defendants' Motion to Dismiss at 18 (Dkt No. 84).

15. Defendants knew that a substantial percentage of all Yasmin and Yaz prescriptions in the United States were paid by the United States through the Medicaid program.

16. Medicaid claims for the payment of off-label Yaz and Yasmin prescriptions are filed with the states by the pharmacists who fill the Medicaid patients' prescriptions. In most cases, the pharmacist will not know whether the prescription is on-label or off-label, and consequently, does not know whether the prescription is for a medically acceptable use, and consequently, a covered outpatient drug under Medicaid. Nonetheless, because such prescriptions for off-label use are not eligible for Medicaid reimbursement, submission of such a claim for reimbursement constitutes a false claim for the purposes of 31 U.S.C. § 3729. A pharmacist who does not know the claim is ineligible has not knowingly submitted a false claim and is not liable to the United States pursuant to § 3729(a). However, a person who *knowingly causes* such a claim to be filed is liable for causing a false claim pursuant to § 3729.

17. Defendants knew that off-label prescriptions of Yaz and Yasmin were not eligible for Medicaid reimbursement. Defendants were aware of the passage of 42 U.S.C. §1396r-8 and its limitations on Medicaid reimbursement for prescription drugs. Notwithstanding Defendants' knowledge that off-label prescriptions of Yaz and Yasmin were not medically accepted uses eligible for Medicaid reimbursement, Defendants knowingly and intentionally took steps to increase the number of off-label Yaz and Yasmin prescriptions submitted to Medicaid. But for Defendants' promotion of off-label uses, most of the ineligible claims for payment of Yaz and Yasmin prescriptions for off-label use would have never been filed. Every off-label Yaz or Yazmin prescription caused by Defendants' off-label promotion of Yaz or Yasmin is a false claim caused by Defendants for the purposes of 31 U.S.C. § 3729.

18. Relator cannot identify at this time all of the false claims which were caused by

defendants' conduct. The false claims were submitted by pharmacists with whom the Relator has had no dealings and the records of the false claims are not within the Relator's control. Indeed, specification of the vast number of false claims would be burdensome to the Court and the parties. Given the vast number of false claims, their scope and complexity, Realtor is excused from the requirement of specifying each false claim. The time period of the false claims, however, was from the launch of defendants' Yasmin and Yaz products to the present.

CLAIM

19. For the reasons stated in paragraphs 8 to 18 above, defendants have violated the False Claims Act by knowingly causing false claims to be made to the United States for off-label uses of its Yasmin and Yaz drug products.

PRAYER FOR RELIEF

Plaintiff thus requests this Court to do the following:

A. Enter judgment against defendants and in favor of plaintiff for the violations alleged in this complaint;

B. Order defendants to pay all costs, fees, awards, and interest permitted by the False Claims Act; and

C. Grant plaintiff such other and further relief as it may deem just and equitable.

JURY DEMAND

Plaintiff demands a jury trial on all issues so triable.

Dated: October 18, 2010

Respectfully submitted,

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